European Commission

Fourth Stakeholder Conference on Biosimilar Medicines
Brussels, 14 September 2018

The role of physicians in prescribing biosimilars and creating opportunities for sustainable cancer care

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the views expressed are the personal views of the presenter and may not be understood or quoted as being made on behalf of or reflecting the position of others

THE (moAb) BIOSIMILARS STORY AS I SEE IT

PAST

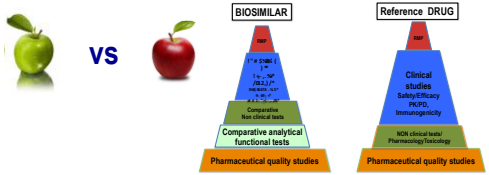
PRESENT

"New" paradigm for drug development

Pivotal trial S&E → COMPARABILITY Ex

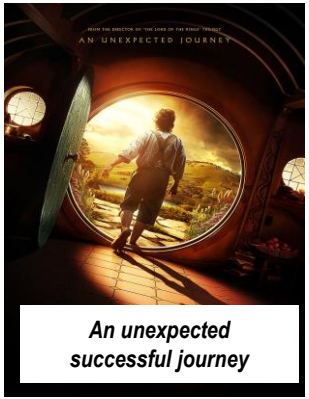
Phase III trial → better performance

-More efficacy
-Less toxicity/ better tolerability
-Both

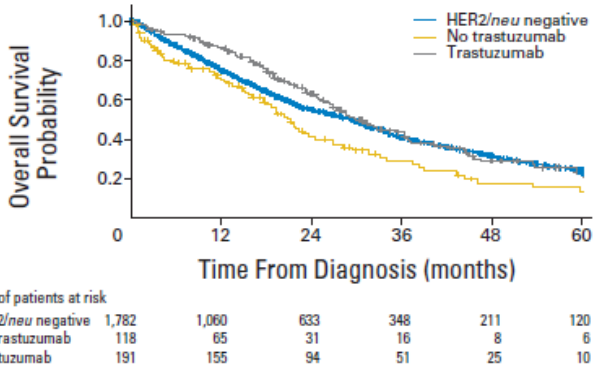


New language + new methodology
Learning curve

FUTURE



An unexpected successful journey



No. of patients at risk

HER2/*neu* negative	1,782	1,060	633	348	211	120
No trastuzumab	118	65	31	16	8	6
Trastuzumab	191	155	94	51	25	10

ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe

Annals of Oncology 27: 1423–1443, 2016

N. Cherny[1]*, R. Sullivan[2], J. Torode[3], M. Saar[4] & A. Eniu[5]

MBC: Actual availability

Country:	3rd+ Hormonal	Her2 +			
	Fulvestrant	Trastuzumab	Pertuzumab	TDM-1	Lapatinib
Austria					
Belgium					
Cyprus					
Denmark					
Finland					
France					
Germany					
Greece					
Holland					
Iceland					
Ireland					
Israel					
Italy					
Luxembourg					
Norway					
Portugal					
Spain					
Sweden					
Switzerland					
Turkey					
United Kingdom					
Albania					
Armenia					
Belarus					
Bosnia and Herzegovina					
Bulgaria					
Croatia					
Czech Republic					
Estonia					
Georgia					
Hungary					
Kazakhstan					
Kosovo, Republic of					
Kyrgyzstan					
Latvia					
Lithuania					
Macedonia					
Malta					
Montenegro					
Poland					
Romania					
Russian Federation					
Serbia					
Slovenia					
Slovakia					
Turkmenistan					
Ukraine					
Uzbekistan					

	Always
	Usually
	Half the time
	Occasionally
	Never
	Not available
	Missing data

MBC: Formulary and cost

Country:	3rd+ Hormonal	Her2 +			
	Fulvestrant	Trastuzumab	Pertuzumab	TDM-1	Lapatinib
Austria					
Belgium					
Cyprus					
Denmark					
Finland					
France					
Germany					
Greece					
Holland					
Iceland					
Ireland					
Israel					
Italy					
Luxembourg					
Norway					
Portugal					
Spain					
Sweden					
Switzerland					
Turkey					
United Kingdom					
Albania					
Armenia					
Belarus					
Bosnia and Herzegovina					
Bulgaria					
Croatia					
Czech Republic					
Estonia					
Georgia					
Hungary					
Kazakhstan					
Kosovo, Republic of					
Kyrgyzstan					
Latvia					
Lithuania					
Macedonia					
Malta					
Montenegro					
Poland					
Romania					
Russian Federation					
Serbia					
Slovenia					
Slovakia					
Turkmenistan					
Ukraine					
Uzbekistan					

	Free
	<25% cost
	25–50% cost
	Discount >50% and <100%
	Full cost
	Not available
	Missing data

Open Access Review

ESMO Open Cancer Horizons

Biosimilars: a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers

Josep Tabernero,[1] Malvika Vyas,[2] Rosa Giuliani,[3] Dirk Arnold,[4] Fatima Cardoso,[5] Paolo G Casali,[6] Andres Cervantes,[7] Alexander MM Eggermont,[8] Alexandru Eniu,[9] Jacek Jassem,[10] George Pentheroudakis,[11] Solange Peters,[12] Stefan Rauh,[13] Christoph C Zielinski,[14] Rolf A Stahel,[15] Emile Voest,[16] Jean-Yves Douillard,[2] Keith McGregor,[2] Fortunato Ciardiello[17]

- Expenditure for medicinal products will be up to 1.3 trillion EUR by 2020
- In the EU, biosimilars are approved by a stringent regulatory process
- When properly developed and prescribed biosimilars represent an

OPPORTUNITY to

-Increase ACCESS to biologic therapies in EU and worldwide
-Lower COSTS
-Contribute to the SUSTAINABILITY of healthcare systems

SWITCHING

REFERENCE PRODUCT → BIOSIMILAR

BIOSIMILAR → REFERENCE PRODUCT

BIOSIMILAR 1 → BIOSIMILAR N

! AUTOMATIC SUBSTITUTION SHOULD BE AVOIDED !

-Physicians are responsible for the act of prescribing medicines
-Patients should be thouroughly and continously informed
-Patients should be closely monitored

EXTRAPOLATION

Analytical, preclinical, PK, PD and clinical data along with immunogenicity should be collected to be correctly extrapolated to all indications of the reference product

EXTRAPOLATION may be **ACCEPTABLE** IF there are enough **RELEVANT DATA** of Safety and Efficacy of the BIOSIMILAR

! EXTRAPOLATION IS A WELL ESTABLISHED SCIENTIFIC PRINCIPLE

BIOSIMILARS_ESMO in Action 2017-2018

Position paper published in Jan 2017

European Commission Stakeholder Event on Biosimilar Medicinal products
Josep Tabernero,
ESMO President, chaired session Collaborative Approach in the Use of Biosimilar Medicines"-May 2017

15° and 16° Biosimilar Conference organized by **Medicines for Europe In 2017 and 2018**
ESMO was represented by Rosa Giuliani who participated in panel discussions

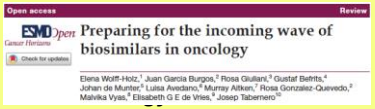
ESMO special session during ESMO 2017 in Madrid: *"The incoming wave of biosimilars in oncology*
700 participants

ESMO Special session during ESMO 2017 in Madrid (700 participants) "The incoming wave of biosimilars In oncology"

ESMO Colloquium on bisosimilars during
ESMO Asia 2017 in Singapore
(≈180 participants)

ESMO meeting with the Biosimilar Medicinal Products Working Party (BMWP) – EMA in London, 21st September 2017

PAPER


Open access Review
ESMO Open Cancer Horizons
Preparing for the incoming wave of biosimilars in oncology
Elena Wolff-Holz,[1] Juan Garcia Burgos,[2] Rosa Giuliani,[3] Gustaf Bellfrits,[4] Johan de Munter,[4] Luisa Avedano,[5] Murray Aitken,[7] Rosa Gonzalez-Quevedo,[7] Malvika Vyas,[8] Elisabeth G E de Vries,[9] Josep Tabernero[10]

(ESMO 2017, Madrid) published on 14 Sept 2018 (yes today!)

ESMO survey on awareness on Biosimilars launched during ESMO 2017 in Madrid. Results to be presented at ESMO 2018 in Munich

European Commission 4° Stakeholder Conference on Biosimilar Medicines
Session_Biosimilar use in Oncology_
14 September 2018

The GLOBAL Atomium

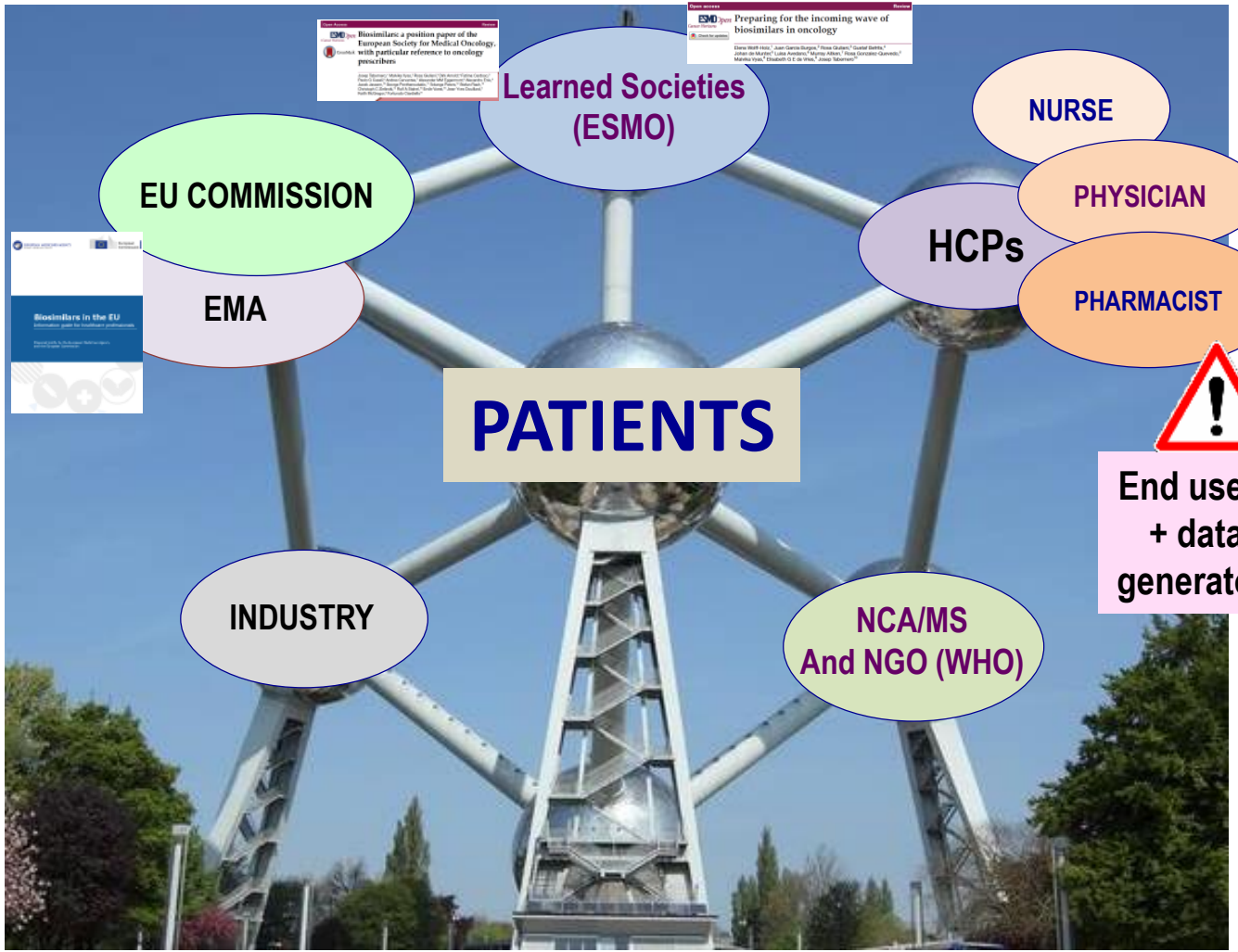
SCIENCE

GUIDANCE

INTERACTION/ COLLABORATION

DATA COLLECTION

DATA ANALYSIS



The LOCAL Atomium

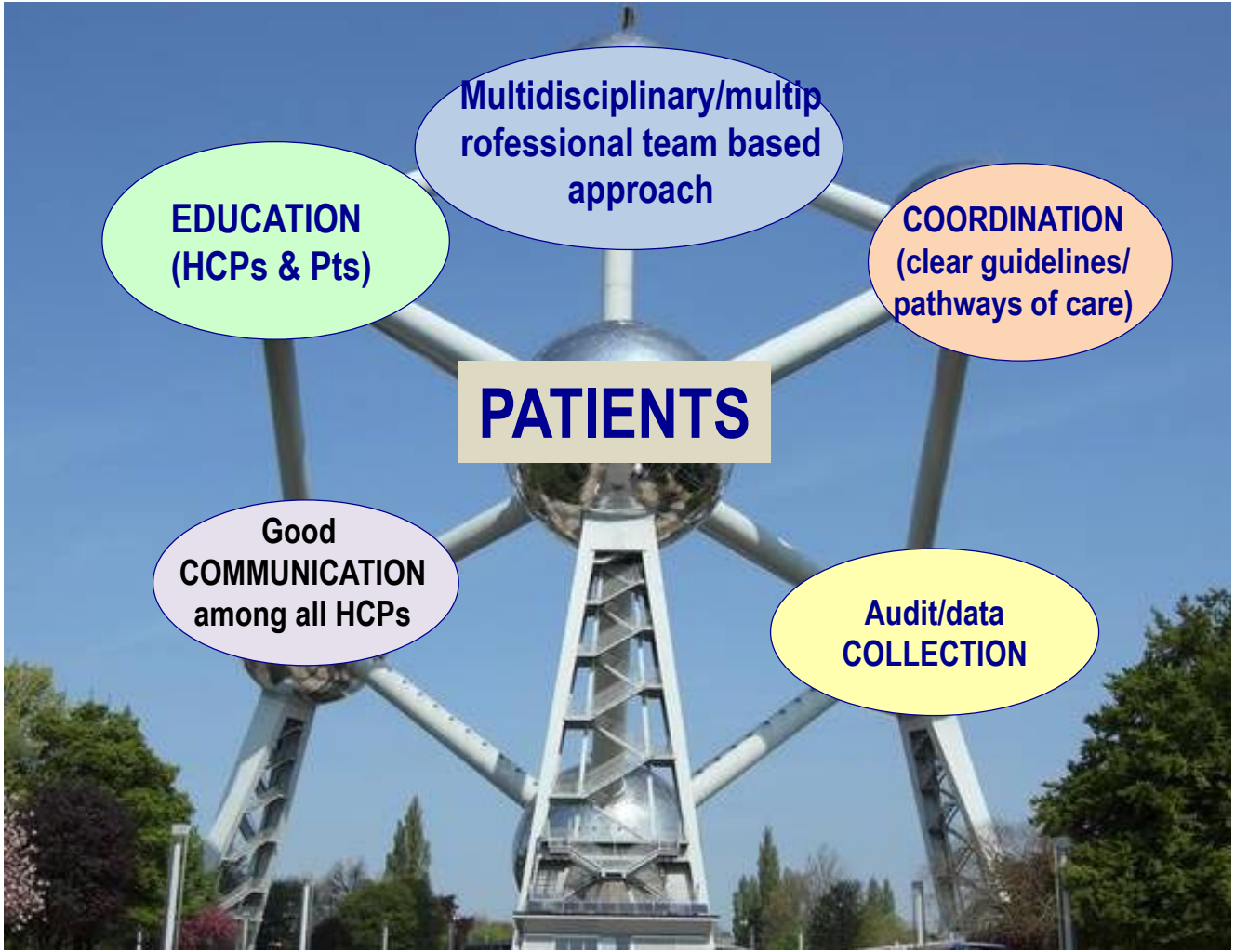
SCIENCE

GUIDANCE

INTERACTION/ COLLABORATION

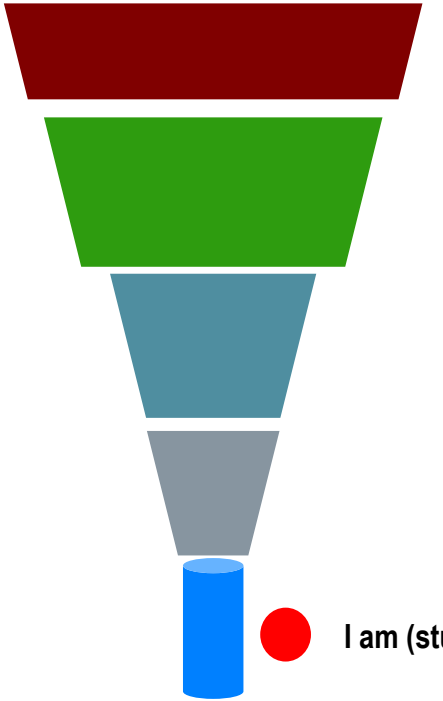
DATA COLLECTION

DATA ANALYSIS



TRANSPARENT Re-ALLOCATION of savings

The "FUNNEL" effect



R&D

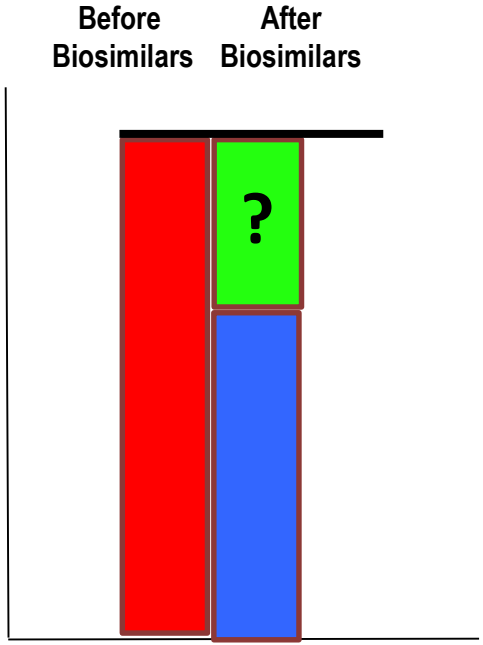
REGULATORS

HTA

PAYERS

I am (stuck) here

HOSPITALS



Adapted from Steinar Madsen, Biosimilar Medicines Conference 2017

EVIDENCE

The EU regulatory process for the assessment of biosimilar medicines is rigorous and leads to the approval of safe and effective drugs.

Collection of post-approval data should be envisioned.

EDUCATION

Concepts (and lexicon!) of comparability exercise, extrapolation and switching "sounded" relatively new, though are now acknowledged.

Guidance from regulators, learned societies, NCA, NGO is key

ENGAGEMENT

Interaction and collaboration among HCPs and with "other bodies" (*and pts of course*) is required for the safe and successful implementation of biosimilars.

It's a team work

SUCCESSFUL IMPLEMENTATION